



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1985d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

## WARNING LETTER

**Certified Mail**  
**Return Receipt Requested**

November 19, 2001

Koreen Phillips  
Mammographer Manager  
San Luis Diagnostic Center  
1100 Monterey Street; Suite #210  
San Luis Obispo, CA 93401-3102

W/L Number: 15 - 02  
Inspection ID: 1887060008  
CFN: 20-30,085  
FEI: 1000519194

Dear Ms Phillips:

We are writing to you because on November 6, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following REPEAT Level 2 finding at your facility:

- Level 2: Failed to produce documents verifying that the radiologic technologist, [REDACTED] (7.5 continuing education units [CEU's] in thirty-six [36] months) met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in thirty-six (36) months. This is a REPEAT violation.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation

Page Two of Three  
November 19, 2001

re: San Luis Diagnostic Center  
re: Warning Letter Number 15 – 02

of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;
- your response should also specifically address the repeat violation which was not corrected from the previous inspection and why it was not corrected prior to the inspection of November 6, 2001;
- each step your facility is taking to prevent the recurrence of similar violations; and
- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd.; Suite #300  
Irvine, CA 92612-2445  
Phone: (949) 798-7600

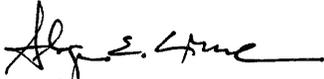
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number 1-800-838-7715) or through the Internet at <http://www.fda.gov>

Page Three of Three  
November 19, 2001

re: San Luis Diagnostic Center  
re: Warning Letter Number 15 – 02

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644..

Sincerely,



Alonza E. Cruse  
District Director

cc:

State of California  
Department of Health Services  
Radiologic Health Branch of San Jose  
100 Paseo de San Antonio; Room #103  
San Jose, CA 95113-1402